IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

DONNA CISSON, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:11-cv-00195

C. R. BARD, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Motion for a New Trial*)

Pending before the court is Defendant C. R. Bard, Inc.'s Motion for a New Trial [Docket 450]; Defendant C. R. Bard, Inc.'s Request for Ruling, or Alternatively for Hearing, on Motion for New Trial [Docket 479]; and Defendant C. R. Bard, Inc.'s Second Request for Ruling, or Alternatively for Hearing, on Motion for New Trial and Motion to Remit Punitive Damages Award and Amend Judgment [Docket 482]. For the reasons discussed below, I **DENY** the defendant's Motion for a New Trial [Docket 450], and as a result, the defendant's Requests for Ruling [Docket 479 & 482] are **DENIED as moot.**[1]

Also before the court is Plaintiffs' Motion to Strike Extraneous Materials Submitted With Bard's Motion for a New Trial ("Motion to Strike") [Docket 458]. For the reasons discussed below, the Motion to Strike is **DENIED as moot**.

[1] The court's disposition on the defendant's motions related to the punitive damages award is fully explained in a separate memorandum opinion and order.

I. Background

This case was the first jury trial within the seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 70,000 cases currently pending, approximately 10,000 of which are in the C. R. Bard, Inc. ("Bard") MDL, MDL 2187. This particular case concerns Donna Cisson, who was implanted with transvaginal surgical mesh—specifically, the Avaulta Plus Posterior Biosynthetic Support System ("Avaulta Plus") manufactured by Bard to treat POP—in May 2009, and after receiving the implant, she experienced "significant mental and physical pain and suffering." (Compl. [Docket 1] ¶ 10). On March 10, 2011, she and her husband (collectively "the plaintiffs") filed suit against Bard for various causes of action, (*id.*), and trial began on July 29, 2013.[2] After fourteen days of trial, the plaintiffs ultimately presented three distinct claims to the jury: design defect, failure to warn, and loss of consortium.

On August 15, 2013, the jury returned a verdict in favor of Ms. Cisson on her design defect and failure to warn claims.[3] In so doing, the jury awarded Ms. Cisson $250,000 in compensatory damages, (Verdict Form [Docket 404] ¶ 4), as well as $1,750,000 in punitive damages, (Verdict Form [Docket 406]). After the trial, I considered and denied Bard's renewed motion for judgment as a matter of law, finding that the plaintiffs' claims had sufficient evidentiary basis such that the jury's verdict was reasonable under Federal Rule of Civil Procedure 50. (Mem. Op. & Order [Docket 448]). Accordingly, I entered judgment in favor of the plaintiffs. (J. Order [Docket 449]).

[2] This case was first tried on July 8, 2013, but resulted in a mistrial. (*See* Trial Tr. July 10, 2013 [Docket 339], at 495:20). The court then moved the trial to July 29, 2013, which produced a verdict.
[3] The jury found that Mr. Cisson had not proven his loss of consortium claim by a preponderance of the evidence.

In a final attempt to absolve itself of the jury's verdict, Bard has moved for a new trial pursuant to Federal Rule of Civil Procedure 59(a)(1). (Mot. for a New Trial [Docket 450]). Anxious to submit its case to the Fourth Circuit Court of Appeals, Bard recently requested a ruling on this motion. (Req. for Ruling, or Alternatively for Hr'g, on Mot. for New Trial [Docket 479] ¶ 4; Second Req. for Ruling, or Alternatively for Hr'g, on Mot. for New Trial and Mot. to Remit Punitive Damages Award and Amend J. [Docket 482]). My ruling is set forth below.

II. Legal Standard

Rule 59 allows a court to grant a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A). The Fourth Circuit has set forth a three-prong standard to govern Rule 59 motions:

> [I]t is the duty of the judge to set aside the verdict and grant a new trial, if he is of the opinion that (1) the verdict is against the clear weight of the evidence, or (2) is based upon evidence which is false, or (3) will result in a miscarriage of justice, even though there may be substantial evidence which would prevent the direction of a verdict.

Atlas Food Sys. & Servs., Inc. v. Crane Nat'l Vendors, Inc., 99 F.3d 587, 594 (4th Cir. 1996) (internal citations and brackets omitted). When considering a motion for a new trial, the "crucial inquiry," particularly when employing the third prong, is "whether an error occurred in the conduct of the trial that was *so grievous* as to have rendered the trial unfair." *Bristol Steel & Iron Works v. Bethlehem Steel Corp.*, 41 F.3d 182, 186 (4th Cir. 1994) (emphasis added).

The decision to grant or deny a new trial "is within the sound discretion of the trial court." *Cline v. Wal-Mart Stores, Inc.*, 144 F.3d 294, 301 (4th Cir. 1998). Moreover, the discretion bestowed under Rule 59 "should be exercised sparingly." *United States v. Arrington*, 757 F.2d 1484, 1486 (4th Cir. 1985); *see also United States v. Perea*, 458 F.2d 535, 536 (10th Cir. 1972) ("A motion for a new trial is generally not regarded with favor, and is granted only

with *great caution*.") (emphasis added). I **FIND** the defendant has fallen far short of clearing this high bar, and I **DENY** its Rule 59 motion.

III. Discussion

> Bard asserts four grounds for a new trial:
>
> (1) The Court deprived Bard of a fair trial by excluding evidence of Bard's compliance with the FDA's 510(k) process and other applicable federal regulations; (2) [t]he Court deprived Bard of a fair trial by admitting the Material Safety Data Sheet ["MSDS"] into evidence and by other evidentiary rulings; (3) [t]he Court's causation rulings deprived Bard of a fair trial; and (4) [t]he Court deprived Bard of a fair trial by allowing Plaintiffs to assert that Bard should have performed pre-market human clinical testing without competent expert testimony to support this claim.

(Mot. for a New Trial [Docket 450], at 1–2). I have addressed each of these concerns in previous orders during the course of this MDL. (*See* Order re: C. R. Bard, Inc.'s Mot. for Clarification & Reconsid. ("Clarification Order") [Docket 309], at 2–4 (excluding evidence of the 510(k) process); Mem. Op. & Order re: Parties' Mots. *in Limine* ("Order Mots. *in Limine*") [Docket 302], at 5–6 (finding that evidence about the MSDS is admissible); Mem. Op. & Order [Docket 448], at 14–19 (concluding that the plaintiffs established causation); Mem. Op. & Order re: Failure to Test [Docket 356], at 4–9 (explaining the relevance of Bard's failure to test)). As such, the plaintiffs contend that Bard is improperly using a Rule 59 motion to "relitigate" old evidentiary issues. (Pls.' Resp. in Opp. to Bard's Mot. for New Trial ("Resp.") [Docket 461], at 1–2 (quoting *In re Miles*, 453 B.R. 449, 450 (Bankr. N.D. Ga. 2011))). The Supreme Court has stated that "alleged substantial errors in admission or rejection of evidence" may warrant a new trial. *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 251 (1940). Thus, this court will entertain the evidentiary challenges raised in Bard's Rule 59 motion. To succeed on this theory, however, Bard must demonstrate that the alleged evidentiary errors were "*substantial*." *Id.* (emphasis added); *see also Creekmore v. Maryview Hosp.*, 662 F.3d. 686, 693 (4th Cir. 2011)

(holding that the court will not set aside a judgment on this basis "unless justice so requires or a party's substantial rights are affected"). As explained below, none of Bard's arguments—taken individually or together—convey the substantial error required to secure a new trial.

A. Exclusion of Bard's Compliance with the FDA's 510(k) Process and "Other Applicable Federal Regulations"

Prior to trial and over Bard's objection, this court excluded evidence of Bard's compliance with the FDA's 510(k) process in marketing the Avaulta Plus on the basis of Federal Rules of Evidence 402 and 403. (*See* Order Mots. *in Limine* [Docket 302], at 3).[4] The court's rationale focused on the Supreme Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996):

> Under United States Supreme Court precedent, the FDA 510(k) process does not go to whether the product is safe and effective. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478–79 (1996); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008). There is ample case law discussing *Lohr* and finding that (1) the 510(k) process does not go to whether the product is safe and effective and (2) the 510(k) process does not impose any requirements on its own. *See, e.g.*, *Martin v. Am. Med. Sys., Inc.*, 116 F.3d 102, 104 (4th Cir. 1997); *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 794 (8th Cir. 2001); *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 747 n.6 (E.D. Pa. 2007); *Nicoll v. I-Flow, LLC*, No. 12-1593, 2013 WL 2477032, at *3 (E.D. La. June 7, 2013); *Mack v. Stryker Corp.*, 893 F. Supp. 2d 976, 985 (D. Minn. 2012). Because the FDA 510(k) process does not go to whether the Avaulta products are safe and effective, and the 510(k) process does not impose any requirements on its own, the 510(k) process is inapplicable to this case. This evidence is excluded under Federal Rule of Evidence 402 as irrelevant, and under Rule 403 [for the] very substantial dangers of misleading the jury and confusing the issues.

(Clarification Order [Docket 309], at 3–4 (internal footnote omitted)). Bard disagrees with this holding and maintains that this court's decision to exclude 510(k) evidence, as well as other FDA evidence, deprived it of a fair trial, preventing Bard from presenting an adequate defense to the plaintiffs' design defect and punitive damages claims. I once again address—and dispose of—

[4] For an explanation of the FDA's 510(k) clearance process, see *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 751–52 (S.D. W. Va. 2014).

these arguments, finding that 510(k) evidence was not relevant to Bard's claims under Rules 401 and 402, and any marginal relevance was substantially outweighed by the risk of confusing and misleading the jury, compelling exclusion under Rule 403.

1. Relevance Under Federal Rules of Evidence 401 and 402

Rule 401 provides that evidence is relevant if "it has a tendency to make a fact more or less probable than it would be without the evidence." Fed. R. Evid. 401. Relevant evidence, "as a general proposition," is admissible. *United States v. Queen*, 132 F.3d 991, 994 (4th Cir. 1997); *see also* Fed. R. Evid. 402 ("Relevant evidence is admissible unless any of the following provides otherwise: . . . ."). Bard contends that its compliance with 510(k) demonstrated the reasonableness of the Avaulta Plus's design and was therefore relevant and admissible evidence. (*See* Def.'s Mem. of Law in Supp. of Mot. for a New Trial ("Def.'s Mem. in Supp.") [Docket 451], at 4–5 (quoting *Volkswagen of Am., Inc. v. Gentry*, 564 S.E.2d 733, 738 (Ga. Ct. App. 2002) (stating that a jury is "entitled to consider the issue of a manufacturer's compliance with federal standards or regulations in determining whether the product design was a reasonable one"))). Given the Supreme Court precedent on the meaning and purpose of 510(k) clearance, Bard's argument fails and cannot support the rarely applied remedy of a new trial.

The Supreme Court has held that compliance with 510(k) focuses on "equivalence, not safety" and that products entering the market through the 510(k) process have "never been formally reviewed [for] safety or efficacy." *Lohr*, 518 U.S. at 493; *Riegel*, 552 U.S. at 322 (explaining that the 510(k) process is an "exemption from federal safety review"). If 510(k) does not go to a product's safety and efficacy—the "very subjects" of the plaintiffs' products liability claims, *id.* at 323—then evidence of Bard's compliance with 510(k) has no relevance in this case and was properly excluded by the court. *See* Fed. R. Evid. 402 ("Irrelevant evidence is not

admissible.").[5] Likewise, Bard's compliance with 510(k) does not make it more or less probable that Bard's conduct justified punitive damages under Georgia law. Georgia's Annotated Code provides for punitive damages when the defendant's actions exhibit "willful misconduct, malice, fraud, wantonness, or oppression." Ga. Code Ann. § 51-12-5.1(b) (2014). Such conduct is not mitigated by compliance with 510(k), a regulation "intended merely to give manufactures the freedom to compete." *Lohr*, 518 U.S. at 492.

At any rate, assuming the court erred on this ruling, Bard has provided no persuasive argument that such an error led to a "miscarriage of justice." In fact, I have applied this ruling in each subsequent MDL trial. *See, e.g.*, *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754 (S.D. W. Va. 2014) (excluding evidence of 510(k) clearance because "[t]hat a device has been given clearance through the FDA's 510(k) process is not relevant to state tort law"); *Sanchez v. Boston Scientific Corp.* (*Sanchez I*), No. 2:12-cv-05762, 2014 WL 4059214, at *15 (S.D. W. Va. Aug. 18, 2014) (same); *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 1883784, at *2 (S.D. W. Va. May 12, 2014) (concluding that the 510(k) process "is irrelevant to [the plaintiff's product liability claims] because it does not relate to safety or efficacy of the product").[6]

[5] Because 510(k) is not a safety regulation, the cases underlying Bard's position are not determinative here. *See Alevromagiros v. Hechinger Co.*, 993 F.2d 417, 420 (4th Cir. 1993) ("In determining what constitutes an unreasonably dangerous defect, a court will consider safety standards promulgated by the government . . . ."); *Stonehocker v. Gen. Motors Corp.*, 587 F.2d 151, 157 (4th Cir. 1978) (stating that evidence of the manufacturer's compliance with a federal safety standard should have been admitted into evidence); *Salmon v. Park, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (concluding that compliance with the federal regulations on the contents of a drug warning is "pertinent" to liability); *Doyle, et al. v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d 518, 519 (Ga. 1997) (considering the preclusive effect of a manufacturer's compliance with the National Automobile Safety Act); *Gentry*, 564 S.E.2d at 736 (allowing evidence regarding the defendant's compliance with the National Traffic and Motor Vehicle Safety Act).

[6] To no avail, Bard continues to challenge this court's reliance on *Lohr* and *Riegel*. First, Bard attempts to diminish this controlling law by pointing to the FDA's publicly released guidance documents. I decline to give these guidances any deference, given that they merely serve as a description of the FDA's "current thinking on a topic" and "do not operate to bind FDA or the public." FDA, *Guidances*, http://www.fda.gov/RegulatoryInformation/Guidances/ (last updated Sept. 19, 2014). Second, Bard tries to overcome this Supreme Court precedent by distinguishing it, asserting that *Lohr*, which focused on federal preemption, should not dictate this court's ruling on the present motion, which focuses on admissibility under Rules 401 and 402. (*See* Def.'s Mem. in Supp. [Docket 451], at 7 ("*Lohr* addressed only whether state law tort claims against the manufacturer of a Class II medical device were expressly preempted, not the admissibility of a manufacturer's compliance with the 510(k) process.")). Bard's

2. Prejudice Under Federal Rule of Evidence 403

The balancing test set forth in Rule 403 also forecloses Bard's arguments in favor of a new trial on the basis of 510(k) exclusion. Rule 403 provides that a court "may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Pursuant to this rule and in exercise of the wide discretion granted under it, *see Sprint/United Mgmt. Co. v. Mendelsohn*, 552 U.S 379, 384 (2008) (explaining that the deferential standard afforded to evidentiary rulings is particularly important under Rule 403 "since it requires an on-the-spot balancing of probative value and prejudice"), this court held that the probative value of 510(k) evidence, if any, was substantially outweighed by the risk of confusing the issues and misleading the jury. (*See* Order Mots. *in Limine* [Docket 302], at 3–4). Bard asserts that this concern was "groundless." (Def.'s Mem. in Supp. [Docket 451], at 10–11).

I disagree and stand by my previous ruling, which I explained further in subsequent cases:

> Evidence regarding the 510(k) process poses a substantial risk of misleading the jury and confusing the issues. That a device has been given clearance through the FDA's 510(k) process is not relevant to state tort law. Admission of any evidence regarding the 510(k) process runs the risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims. The prejudicial value of evidence regarding the 510(k) process far outweighs its

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argument, however, mistakenly treats preemption under the Federal Food, Drug, and Cosmetic Act ("FDCA") and admissibility under the Federal Rules of Evidence as mutually exclusive concepts when in fact, both hinge on whether 510(k) relates to the safety and effectiveness of a medical device. In concluding that 510(k) does not have preemptive effect under the FDCA, the *Lohr* Court first determined that the 510(k) process (1) does not impose device-specific requirements on its own and (2) does not relate to safety or effectiveness. *See Lohr*, 518 U.S. at 493–94. Because 510(k) does not relate to safety, it follows that 510(k) clearance of the Avaulta Plus does not speak to the "gravity and severity of the danger posed by the design; the likelihood of that danger; [and] the avoidability of the danger," which are factors Georgia courts generally consider when faced with design defect claims. *Banks v. ICI Ams., Inc.*, 450 S.E.2d 671, 675 n.6 (Ga. 1994). In this way, *Lohr*'s preemption analysis, though not speaking directly to relevance, nevertheless prompted the admissibility ruling in this case, resulting in the exclusion of 510(k) evidence under Rule 402.

> probative value. . . . Jurors are likely to believe that FDA enforcement relates to the validity of the plaintiffs' state law tort claims, which it does not. [Furthermore,] the jury may attach undue significance to an FDA determination, and [] alleged shortcomings in FDA procedures are not probative to a state law products liability claim.

Lewis, 991 F. Supp. 2d at 754–55 (internal quotations omitted); *see also Sanchez v. Boston Scientific Corp. (Sanchez II)*, No. 2:12-cv-05762, 2014 WL 4851989, at *35 ("[T]estimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about the [state law claims] than enlightenment."). In addition, allowing 510(k) evidence would have provoked the parties to engage in a time-consuming mini-trial on whether Bard in fact complied with its provisions.[7] Excluding 510(k) evidence avoided these risks and was therefore proper under Rule 403.

Bard also contends that the court's exclusion of 510(k) compliance "exacerbated prejudice" by preventing Bard from defending its decision not to conduct premarket human clinical trials. (Def.'s Mem. in Supp. [Docket 451], at 11). My pretrial ruling adequately addresses this matter, and I adopt it here:

> The FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own. Basically, it has no . . . operative interaction with state tort laws. Whether the FDA 510(k) process required testing before or after marketing has nothing to do with whether Bard satisfied any other obligation under common law to conduct testing and then to do whatever it might have been required to do under law with the results of that testing. . . . In sum, Bard had a duty to test the Avaulta product as part of the risk-utility analysis assessing the reasonableness of its conduct independent of the FDA 510(k) process.

(Mem. Op. & Order re: Failure to Test [Docket 356], at 12–13).

[7] Although Bard asserts that such a mini-trial would not have developed, the back-and-forth on this issue both prior to and after trial has justified my fears. (*See* Order Mots. *in Limine* [Docket 302], at 4 ("Given the parties' filings throughout this case, it is abundantly clear that there would be a substantial mini-trial on the 510(k) process and enforcement should it be allowed."); Resp. [Docket 461], at 11 n.2 (insisting that had the court allowed Bard to introduce FDA clearance, plaintiffs would have responded with evidence regarding the FDA's recent concerns with the safety of pelvic mesh products)).

In sum, even if 510(k) compliance satisfied the relevance standard of Rule 401, the substantial risk of misleading the jury and wasting judicial resources by diving into a morass of FDA regulations—none of which relate to the state law claims at issue—weighed heavily in favor of exclusion. I therefore **FIND** that the exclusion of 510(k) evidence does not warrant a new trial.[8]

3. Motion to Strike

Before turning to Bard's next argument, I quickly address the plaintiffs' Motion to Strike [Docket 458], which I consider as merely an additional objection to Bard's Motion for a New Trial on the basis of the court's exclusion of 510(k) evidence. The plaintiffs challenge four exhibits attached to Bard's Motion for a New Trial as "extraneous" evidence that should not be considered by the court at this stage, given that Bard did not make an appropriate offer of proof at trial. (Mot. to Strike [Docket 458], at 1). In response, Bard asserts that an offer of proof on these exhibits was unnecessary under Federal Rule of Evidence 103(b), and as such, the "documents at issue are within the scope of the court's ruling." (Mem. of Law in Opp. to Pls.' Mot. to Strike [Docket 467], at 6). Quarrels about the adequacy of an offer of proof have a time and place, but it is not here. I have not considered the documents attached to Bard's Motion for a

[8] Though the above discussion focuses exclusively on Bard's compliance with 510(k), the same rationale under Rule 403 applies to the court's exclusion of other federal regulations that *do* relate to safety and effectiveness. (*See* Def.'s Mem. in Supp. [Docket 451], at 5 (asserting that the court wrongly excluded Bard's compliance with other federal regulations, including "quality system requirements," "design requirements," and "specific labeling regulations")). Even if these regulations go to safety and effectiveness, as Bard suggests, evidence of compliance is not automatically admissible. *See* Fed. R. Evid. 402 advisory committee notes ("[N]ot all relevant evidence is admissible."); Fed. R. Evid. 403 (providing that the court may exclude evidence if its probative value is substantially outweighed by the risk of confusing the issues or misleading the jury, among other things). At trial, I ruled that allowing the attorneys to "go down the road of federal regulatory schemes" would risk confusing and misleading the jury. (Trial Tr. July 29, 2013 [Docket 362], at 209:1–3). I see no reason to deviate from this ruling. Indeed, I have held similarly in every other MDL case. *See, e.g.*, *Sanchez II*, 2014 WL 4851989, at *35 (ruling that evidence about "the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about the failure-to-warn claim than enlightenment"); *Lewis*, 991 F. Supp. 2d at 755 (ruling that introducing evidence of FDA regulations may result in the jury "attach[ing] undue significance to an FDA determination"). Given that the probative value of evidence on regulatory compliance is substantially outweighed by the risk of jury confusion, the court properly excluded such evidence under Rule 403.

New Trial, nor am I willing to consider these documents, as they concern subjects that I have excluded as minimally relevant and extremely misleading. Thus, I **DENY as moot** the plaintiffs' Motion to Strike [Docket 458].

B. Admission of the Material Safety Data Sheet

In its initial motions *in limine*, Bard moved to preclude any evidence or argument concerning the MSDS that accompanied the polypropylene resin material used to manufacture the Avaulta Plus. (*See* Def. C. R. Bard, Inc.'s Initial Mots. *in Limine* [Docket 268], at 4).[9] The MSDS states, in relevant part, as follows:

> MEDICAL APPLICATION CAUTION: Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

(*Id.* at 6). I denied Bard's motion *in limine*, finding that to the extent the plaintiffs offered the MSDS for the truth of the matter asserted, it was admissible under several hearsay exceptions:

> The MSDS falls within the hearsay exception found in Rule 803(17) as an "other compilation[] that [is] generally relied on by the public or by persons in particular occupations." Fed. R. Evid. 803(17). [And t]o the extent that the plaintiffs introduce the statements in the MSDS through an expert witness, the statements fall within the hearsay exception found in Rule 803(18) as a "statement contained in a . . . pamphlet." Fed. R. Evid. 803(18). Finally, the MSDS falls within the residual hearsay exception under Rule 807.

(Order Mots. *in Limine* [Docket 302], at 4–5). Bard now argues that even if the MSDS satisfied a hearsay exception, "its probative value is substantially outweighed by the danger of unfair prejudice to Bard," and as such, "the Court should have excluded it under Fed. R. Evid. 403." (Def.'s Mem. in Supp. [Docket 451], at 14).

[9] Federal law requires chemical manufacturers, distributers, or importers to "develop a safety data sheet for each hazardous chemical they produce or import." 29 C.F.R. § 19010.1200(g)(1) (2014). This material safety data sheet, known as an "MSDS," must include various data about the chemical, including its composition and ingredients, physical and chemical properties, and toxicological information. *Id.* § 19010.1200(g)(2).

I disagree. As previously explained, evidence has probative value if it "has any tendency to make a fact more or less probable than it would be without the evidence." Fed. R. Evid. 401(a). Here, the MSDS, which cautions against using the polypropylene resin in a permanent medical implant, bolstered many of the plaintiffs' claims, making them more probable than not. For instance, the MSDS demonstrated that Bard had knowledge about certain risks of the Avaulta Plus that it did not communicate to implanting physicians, therefore providing support for the plaintiffs' failure to warn claim. (*See, e.g.*, Trial Tr. July 30, 2013 [Docket 365], at 110:8–9 (introducing testimony of Ms. Cisson's implanting physician, Dr. Raybon, who was "astounded" when he saw the MSDS)). Bard's disregard of the risks presented in the MSDS also provided evidence of willful misconduct and wantonness that furthered an award of punitive damages. (*See* Trial Tr. Aug. 7, 2013 [Docket 377], at 60:24–61:2 (introducing testimony that Mr. Darois, the Vice President of Research and Development for the Davol division of Bard, did not perform further studies after becoming aware of the MSDS in 2007)); *see also Sanchez I*, 2014 WL 4059214, at *13 ("A reasonable jury could find that by ignoring a warning on the MSDS and failing to conduct clinical testing, BSC's actions were despicable conduct with willful and conscious disregard of the safety of consumers."). Therefore, the MSDS tended to make more probable than not the plaintiffs' claims for failure to warn and punitive damages, and Bard has not demonstrated that this probative value collapses under Rule 403. Moreover, Bard has provided no arguments indicating that this ruling was "substantial[ly] erro[neous]" such that a new trial should be ordered.

I do not find any of Bard's other arguments on this issue meritorious. First, Bard contends that the court's exclusion of FDA compliance prevented Bard from explaining to the jury that disregarding the MSDS "was reasonable" under the FDA's regulatory framework,

which focuses on the safety of "finished medical devices, not the raw material." (Def.'s Mem. in Supp. [Docket 451], at 15). Because Bard was able to make this point without referring to the FDA, there is no reason to order a new trial on this basis. (*See, e.g.*, Trial Tr. Aug. 7, 2013 [Docket 377], at 81:3–82:6 (providing testimony of Mr. Darois, who explained to the jury that the MSDS provides "warnings and precautions for people that are handling the [resin] pellets and is not meant to apply to the finished polypropylene mesh product")).

Second, Bard claims that the court's exclusion of 510(k) evidence unfairly prevented Bard from demonstrating that the FDA knew about and considered the MSDS at issue in its 510(k) evaluation of the Avaulta Plus. (*See* Def.'s Mem. in Supp. [Docket 451], at 16). This argument "exaggerates the importance of the § 510(k) process." *Lohr*, 518 U.S. at 492. No matter the materials reviewed by the FDA in the 510(k) process, the result is the same—510(k) clearance does not speak to the safety and effectiveness of a product or the raw materials forming it. *See id.* at 493 (holding that the 510(k) review process focuses on "equivalence, not safety"). The FDA's consideration of the MSDS therefore had little probative value and served only to confuse the jury.

Third, Bard disputes the court's exclusion of other manufacturers' use of polypropylene in violation of the MSDS, asserting that Georgia law allows a jury to consider industry-wide practices in determining products liability. (*See* Def.'s Mem. in Supp. [Docket 451], at 16 (quoting *Barger v. Garden Way, Inc.*, 499 S.E.2d 737, 743 (Ga. Ct. App. 1998))). At trial, I excluded other manufacturers' treatment of the MSDS in order to "avoid disentangling" this case with other pelvic mesh cases existing within these MDLs. (Trial Tr. Aug. 7, 2013 [Docket 377], at 221:10–11). I did not want to confuse the jury by "open[ing] up all the other lawsuits." (*Id.* at 221:11–12). This reasoning under Rule 403 still applies a year later—indeed, the risk of

confusing the jury with the existence of other pending lawsuits is arguably greater now, given the increased public awareness of pelvic mesh litigation.

Last, Bard argues that the court's exclusion of Dr. Maureen Reitman's expert opinion on the MSDS prevented Bard from responding to the "accusations" arising from Bard's treatment of the MSDS. (Def.'s Mem. in Supp. [Docket 451], at 16). This argument is not convincing, given that the court properly excluded Dr. Reitman's opinion on the MSDS—which was not included in her expert report—pursuant to Federal Rules of Civil Procedure 26(2)(B) and 37(c)(1). *See* Fed. R. Civ. P. 26(a)(2)(B) (requiring parties to disclose "a complete statement of all opinions [an expert] witness will express"); Fed. R. Civ. P. 37(c)(1) (providing that if a party fails to provide information as required by Rule 26(a), then the party cannot use that information at trial).

To summarize, Bard has not demonstrated that the admission of the MSDS resulted in a miscarriage of justice, and accordingly, I **FIND** that a new trial is not warranted on this point.

C. Causation Rulings

Next, Bard challenges the court's rulings related to causation, beginning with the court's "refus[al] to instruct the jury that, under Georgia law, plaintiffs were required to prove causation by expert testimony stated to a reasonable degree of medical certainty." (Def.'s Mem. in Supp. [Docket 451], at 17). Although providing the jury with improper instructions can justify a new trial, *see Wyatt v. Interstate & Ocean Transp. Co.*, 623 F.2d 888, 892 (4th Cir. 1980), *disapproved of on other grounds*, *Bowen v. U.S. Postal Serv.*, 459 U.S. 212 (1983) (affirming the district court's action of granting a new trial "because the jury was improperly instructed on the question of liability and reached their decision under an incomplete theory of law"), the court did

not provide improper instructions in this case. The court instructed the jury as directed by the Georgia Suggested Pattern Jury Instructions, nearly word-for-word:

> Proximate cause is that which, in natural and continuous sequence, unbroken by other causes, produces an event and without which the event would not have occurred. Proximate cause is that which is nearest in the order of responsible causes (as distinguished from remote) that which stands last in causation, not necessarily in time or place, but in causal relation. . . . A plaintiff bears the burden of proof in showing proximate cause by a preponderance of the evidence. . . .
>
> To recover damages, a person injured by an allegedly defective product must establish the following three elements by a preponderance of the evidence: (1) The product was in fact defective; (2) the defect existed at the time the product left the manufacturer's control, and (3) the defect in the product was a proximate cause of the plaintiff's injury. . . .

(Final Jury Instructions [Docket 399], at 9–10); *see also* Ga. Suggested Pattern Jury Instructions, Vol. I: Civil Cases §§ 60.200 & 62.610 (5th ed.) (providing the instructions used at this trial). The Georgia Suggested Pattern Jury Instructions do not require the court to instruct the jury that causation must be established through competent expert testimony to a reasonable degree of medical certainty, nor does any Georgia case require this language. *See Toole v. Ga.-Pac., LLC*, No. A10A2179, 2011 WL 7938847, at *2 (Ga. Ct. App. Jan. 19, 2011) (explaining that the defendant's experts "rendered competent medical opinions even though they did not use the phrase 'to a reasonable degree of medical certainty'" (citing *Beasley v. Northside Hosp., Inc.*, 658 S.E.2d 233, 237 (Ga. Ct. App. 2008), *Ambling Mgmt. Co. v. Purdy*, 640 S.E.2d 620, 627 (Ga. Ct. App. 2006), and *Brown v. Hove*, 603 S.E.2d 63, 65 (Ga. Ct. App. 2004))).

In addition, Bard contends that while the plaintiffs presented "three theories of design defect," they only supported one of the alleged defects—the placement of the device's arms—with causation evidence sufficient to put the issue before a jury. (Def.'s Reply Mem. of Law in Supp. of Mot. for a New Trial [Docket 469], at 18). As to the plaintiffs' other theories of design defect concerning pore size and use of polypropylene, Bard argues that "there was no evidence"

of proximate causation, and so the court should not have allowed the jury to consider them. (*Id.*). I have previously addressed this argument, and, finding no further explanation necessary, I adopt it here:

> [T]he plaintiffs were not required to separate the alleged defects as Bard now attempts to do. Georgia law provides that in a products liability case "it is not necessary for the plaintiff to specify precisely the nature of the defect." *Trickett v. Advanced Neuromodulation Sys., Inc.*, 542 F. Supp. 2d 1338, 1345 (S.D. Ga. 2008); *see also, e.g., Williams v. Am. Med. Sys.*, 548 S.E.2d 371, 374 (Ga. Ct. App. 2001); *Waddy v. Globus Med., Inc.*, No. 407CV075, 2008 U.S. Dist. LEXIS 73030, at *12 (S.D. Ga. Aug. 18, 2008). What a plaintiff must show is that "the device did not operate as intended and this was the proximate cause of [the plaintiff's] injuries." *Trickett*, 542 F. Supp. 2d at 1345.
>
> Using this logic, it was not necessary for the plaintiffs to specify the exact defect in the Avaulta Plus that injured Ms. Cisson, as long as they presented evidence to demonstrate that the device did not function as intended, and that it proximately caused Ms. Cisson's injuries. Therefore, if the plaintiffs presented evidence of *any* design defect in the Avaulta Plus and presented evidence to show that the defect proximately caused Ms. Cisson's injuries, the case must go to the jury. The plaintiffs did not allege three separate design defect claims related to the arms, polypropylene, and pore size; they argued that the Avaulta Plus was defectively designed. Similarly, there was one jury instruction for design defect, not three.
>
> The issue of whether the arms in the Avaulta Plus constitute a design defect cannot be separated from the design defect claim as a whole, as Bard now attempts to assert. Where a plaintiff has presented *any* evidence of a design defect, judgment as a matter of law rarely will be granted. *See, e.g., Ogletree v. Navistar Int'l Transp. Corp.*, 522 S.E.2d 467, 470 (Ga. 1998) (stating that the risk-utility test used in Georgia to determine whether a product was defectively designed "increased the burden of a defendant, in seeking a judgment as a matter of law, to show plainly and indisputably an absence of any evidence that a product as designed is defective"); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1365 (M.D. Ga. 2010) ("In general, weighing the risk-utility factors is left to the jury. Judgment as a matter of law will rarely be granted in design defect cases when any of the elements is disputed."). Here, the plaintiffs presented evidence showing that, because of the arms on the device, the Avaulta plus was defectively designed. This was conceded by Bard in its Rule 50(a) motion. Therefore, judgment as a matter of law is not appropriate on the design defect claim.

(Mem. Op. & Order [Docket 448], at 7–9).[10]

I therefore **FIND** that neither the court's jury instruction on causation nor the court's submission of the design defect claim to the jury resulted in a "substantial" error that would require a new trial.

D. Admission of Testimony on Premarket Human Clinical Testing

Finally, Bard asks this court to grant its motion because the plaintiffs' "allegations regarding Bard's decision to not perform premarket clinical testing should not have been allowed to proceed to trial." (Def.'s Mem. in Supp. [Docket 451], at 20). In Bard's view, "the incomplete presentation of evidence on clinical testing effective[ly] imposed a legal duty to test upon Bard where none existed, thereby "inflaming the jury's prejudice." (*Id.*). To the extent that I am able to parse Bard's rather disorganized prose, I find it unpersuasive and readily addressed by my prior rulings. I have previously explained the relevance of preclinical testing to claims of design defect and failure to warn:

> While there is no *claim* for failure to test under Georgia law, under the risk-utility analysis for design defects, the duty to exercise reasonable care includes the duty to test the product. *See, e.g.*, *Lillebo v. Zimmer, Inc.*, No. 03-2919 (JRT/FLN), 2005 WL 388598, at *8 (D. Minn. 2005); *Nicklaus v. Hughes Tool Co.*, 417 F.2d 983, 986 (8th Cir. 1969); *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1089–90 (5th Cir. 1973); *Dartez v. Fibreboard Corp.*, 765 F.2d 456, 461 (5th Cir. 1985); *Nicholson v. Am. Safety Util. Corp.*, 476 S.E.2d 672, 676 (N.C. Ct. App. 1996); *Hensley v. Danek Med., Inc.*, 32 F. Supp. 2d 345, 351 (W.D.N.C. 1998); *see also* Restatement (Third) of Torts: Prod. Liab. § 2 cmt. m. (1998) ("Of course, a seller bears responsibility to perform reasonable testing prior to marketing a

[10] Bard argues that the court "applied the wrong standard" when relying on *Trickett* to reach this conclusion because *Trickett*'s rationale applies only to claims of manufacturing defect and not to claims of design defect. (Def.'s Mem. in Supp. [Docket 451], at 17–18). I do not find this argument persuasive. The logic set forth in *Trickett*, though not expressly referring to design defect claims, equally applies in this case, where, as in *Trickett*, the plaintiffs have provided evidence that the device "did not operate as intended," resulting in the plaintiff's injuries. *Trickett*, 542 F. Supp. 2d at 1345; *see also Waddy*, 2008 U.S. Dist. LEXIS 73030, at *12 (explaining that the plaintiffs' "inability to determine a specific defect in the [product] is not fatal to his [strict liability] claims"). In any event, assuming that the court incorrectly relied on *Trickett*, as Bard suggests, the court's decision to send the plaintiffs' design defect claim to the jury was not "so grievous as to render the trial unfair," *Bristol Steel & Iron Works v. Bethlehem Steel Corp.*, 41 F.3d 182, 186 (4th Cir. 1994), considering Bard's failure to "show plainly and indisputably an absence of evidence that a product as designed is defective." *Ogletree*, 522 S.E.2d at 470.

> product and to discover risks and risk-avoidance measures that such testing would reveal."). . . .
>
> The duty to test is subsumed within the plaintiffs' design defect and failure to warn claims. *See, e.g.*, *Lillebo*, 2005 WL 388598, at *8 (duty to test as part of risk-utility analysis); *Wagoner v. Exxon Mobil Corp.*, 813 F. Supp. 2d 771, 793–94 (E.D. La. 2011) (duty to test as part of duty to warn).

(Mem. Op. & Order re: Failure to Test [Docket 356], at 6–9).[11] Additionally, no "fundamental prejudice" resulted from allowing evidence on preclinical testing while simultaneously prohibiting Bard from explaining the "regulatory framework" for its actions, (Def.'s Mem. in Supp. [Docket 451], at 20), given that "Bard had a duty to test the Avaulta product as part of the risk-utility analysis assessing the reasonableness of its conduct independent of the [federal regulatory] process," (Mem. Op. & Order re: Failure to Test [Docket 356], at 13).

For these reasons, I **FIND** that the court's decision to admit evidence on Bard's failure to conduct testing does not call for a new trial.

IV. Conclusion

The arguments advanced in support of a new trial are unpersuasive. Crucially, none of the objections raised by Bard constitutes an error "so grievous as to have rendered the trial unfair." *Bristol Steel & Iron Works v. Bethlehem Steel Corp.*, 41 F.3d 182, 186 (4th Cir. 1994). On the contrary, the evidentiary decisions made during this trial ensured that the jury would hear the most probative evidence from each side without being confused and misled by superfluous and complicated testimony. Thus, applying the hesitancy and caution that a district court must

[11] Indeed, the Georgia Pattern Jury Instructions indicate the relevance of clinical testing to these strict liability claims. With respect to a design defect claim, whether a manufacturer tested a product can substantiate or invalidate several of the factors within Georgia's risk-utility analysis, such as "the severity of the danger posed by the design," "the likelihood of that danger," and the "ability to eliminate the danger without impairing the product's usefulness." Ga. Suggested Pattern Jury Instructions, Vol. I: Civil Cases § 62.650 (5th ed.). And with respect to a failure-to-warn claim, whether a manufacturer assessed a product's "potential dangers" can demonstrate the adequacy or inadequacy of the product's accompanying warnings. *Id.* § 62.680.

employ in these circumstances, this court **DENIES** Bard's Motion for a New Trial [Docket 450] and **DENIES as moot** Bard's subsequent requests for ruling [Docket 479 & 482].

Furthermore, for the reasons explained above, the court **DENIES as moot** the plaintiffs' Motion to Strike [Docket 458].

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: January 20, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE